CASE D0115NP

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF

FEDER ET AL.

APPLICATION NO: 10/086,156

FILED: FEBRUARY 28, 2002

FOR: POLYNUCLEOTIDE ENCODING TWO NOVEL HUMAN AND POTASSIUM CHANNEL BETA-SUBUNITS, K+betaM4 AND K+betaM5

Art Unit: 1636

Examiner: WEGERT, SANDRA L.

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 CFR §1.192

Sir:

Applicants appeal to the Board of Appeals from a decision mailed August 12, 2003, in which the Examiner finally rejected claims 21-32 and 34-40 of the above-identified application. Applicants timely filed a Notice of Appeal on November 12, 2003. The present brief is being filed in support of that Notice of Appeal.

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The filing date of the Notice of Appeal was November 12, 2003. Therefore, this brief was due January 12, 2004 under 37 C.F.R. §1.192(a). A Petition for a One (1) Month Extension of Time is being filed herewith under 37 C.F.R. §1.136(a), thereby extending the due date for filing this brief until February 12, 2004.

Applicants request that the Patent Office charge $440.00 to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company. This amount reflects the fee of $330.00 set forth in 37 C.F.R. §1.17(c) associated with filing a brief in support of an appeal, and the $110.00 fee for a One (1) Month Extension of Time set forth in 37 C.F.R. §1.17(a)(1). As required by 37 C.F.R. §1.192(a), this brief is being filed in triplicate.

Although it is believed no additional fee is due, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment associated with the filing of this correspondence to Deposit Account Number 19-3880. Furthermore, if any extension of time not already accounted for is required, such extension is hereby petitioned for, and it is requested that any fee due for said extension be charged to Deposit Account Number 19-3880.

(1) REAL PARTY IN INTEREST

Applicants John N. Feder, Liana Lee, Jian Chen, Donald Jackson, Chandra S. Ramanathan, Nathan O. Siemers, Han Chang and Pamela Carroll filed this application on February 28, 2002. The real party in interest in the present appeal is Bristol-Myers Squibb Company, having acquired rights from the aforementioned applicants by way of an Assignment recorded on May 13, 2002 at Reel 012894, Frame 0332, which was corrected on October 31, 2002 at Reel 013453, Frame 0942.

(2) RELATED APPEALS AND INTERFERENCES

Applicants and applicants' legal representative are unaware of any related appeals or interferences that will directly affect, be directly affected by or have a bearing on the Board's decision in the instant appeal.

(3) STATUS OF CLAIMS

Claims 1-20 were cancelled.

Claims 21-40 are presently pending in the application.

Claims 21-32 and 34-40 are under consideration and have been examined.

Claim 33 has been withdrawn from consideration.

Claims 21-32 and 34-40 stand finally rejected under 35 U.S.C. §101 as lacking utility.

Claims 21-32 and 34-40 also stand finally rejected under 35 U.S.C. §112, first paragraph, as not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 stands finally rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

The rejections of Claims 21-32 and 34-40 are being appealed.

(4) STATUS OF AMENDMENTS

In an Office Action dated August 12, 2003, the Examiner finally rejected claims 21-32 and 33-40. In response thereto, applicants subsequently filed an Amendment After Final Rejection on November 12, 2003 presenting amendments to element (e) of claim 21 and arguments in response to the outstanding grounds of rejection. Applicants have not yet received an Advisory Action in response to the November 12, 2003 Amendment After Final Rejection.

(5) SUMMARY OF INVENTION

In accordance with claim 21 of the patent application now on appeal, the present invention is directed to an isolated nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of:

(a) an isolated polynucleotide encoding a polypeptide comprising amino acids 1 to 343 of SEQ ID NO:24 including the start codon;

(b) an isolated polynucleotide encoding a polypeptide comprising amino acids 2 to 343 of SEQ ID NO:24 minus the start codon;

(c) an isolated polynucleotide encoding a polypeptide comprising amino acids 146 to 241 of SEQ ID NO:24;

(d) an isolated polynucleotide which represents the complimentary sequence of (a), (b), (c), or fragment thereof; and

(e) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(d), wherein said polynucleotide does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues.

The present invention is also directed to vectors comprising nucleic acid molecules encoding K+betaM5 and derivatives, variants and fragments thereof, and host vector systems comprising such vectors, as described in claims 22-32 and 34-40.

Claims 22-32 and 34-40 depend directly or indirectly from claim 21.

The claimed K+betaM5 polypeptide sequence was determined to share 20.0% identity and 40.0% similarity with the human Maxi-K potassium channel beta subunit, KCNMB1 (Genbank Accession No. gi|4758625), 31.7% identity and 43.4% similarity with the human potassium channel K+Hnov28 protein (Genbank Accession No. gi| Y34129), 34.4% identity and 45.6% similarity with the human lung protein, MGC:2376 (Genbank Accession No. gi|12654469), 31.7% identity and 43.4% similarity with the human MSTP028 protein (Genbank Accession No. gi|11640564); to share 34.4% identity and 45.6% similarity with the Caenorhabditis K+ channel tetramerisation domain containing protein (K+channel_tetra; Genbank Accession No. gi|3875362); and to share 30.8% identity and 38.3% similarity with the Drosophila CG10465 protein (Genbank Accession No. gi|7302243).

(6) ISSUES

The issues on appeal are:

A. Whether the claimed invention lacks utility, when the Specification recites numerous uses for the claimed K+betaM5 sequences, the function of which is demonstrated and exemplified in the Specification.

B. Whether the claimed invention is described sufficiently to enable one of ordinary skill in the art to make and use the claimed invention, when the invention is supported by at least one specific, substantial and credible utility and guidance is provided in the Specification as to how to employ the claimed invention for the asserted uses.

C. Whether the recitation of the term "stringent" in claim 21 renders the claim indefinite, when the term "stringent" is defined explicitly and discussed in the Specification.

(7) GROUPING OF CLAIMS

The claims stand or fall together on the contested grounds of rejection, for the sole purpose of allowing the Board to select a single claim for review, and to decide the appeal as to the grounds of rejection on the basis of that claim alone.

(8) ARGUMENT

A. CLAIMS 21-32 AND 34-40 RECITE A NUMEROUS USES FOR THE CLAIMED AND CHARACTERIZED K+BETAM5 SEQUENCES, THEREBY MEETING THE REQUIREMENT OF 35 U.S.C. §101

In the Final Rejection, the Patent Office maintained the rejection of Claim 21-32 and 34-40 under 35 U.S.C. §101 as lacking utility, alleging that the claimed invention is not supported by either a specific, substantial and credible asserted utility, or a well-established utility. In the Final Rejection, the Patent Office argued "The skilled artisan is not provided with sufficient guidance to use the claimed polynucleotides for any purpose unique to this channel." Final Rejection, page 4. Applicants respectfully disagree.

The standards required by the Patent Office for satisfying 35 U.S.C. §101 utility are set forth in the Utility Examination Guidelines (Federal Register, Vol. 66, No. 6, pages 1092-1099, Friday, January 5, 2001). Particularly, in order to satisfy 35 U.S.C. §101, the specification must set forth at least one specific, substantial and credible utility for the claimed invention. Applicants have complied with this requirement.

As applicants noted in their responses, under the Utility Examination Guidelines, if applicants have asserted that the claimed invention is useful for just one practical purpose (i.e., it has a "specific and substantial utility"), and that the asserted utility would be considered credible by a person of ordinary skill in the art, then the utility requirement of 35 U.S.C. §101 is satisfied. Applicants submit this requirement has clearly been met in the present case.

Apparently, the Patent Office's final rejection of the claims is based on the Patent Office's perceived failure of applicants to disclose properties of the claimed polynucleotides and polynucleotides sufficient to support an inference of utility. However, applicants note that this is

not the only way to meet the standard for utility mandated by 35 U.S.C. §101. Under the present law, homology to a molecule with known utility is acceptable for establishing utility under 35 U.S.C. §101, as outlined in Fujikawa v. Wattanasin, 93 F.3d 1559 (Fed. Cir. 1996), as recited in the Utility Examination Guidelines ("When a patent application claiming a nucleic acid asserts a specific, substantial and credible utility, and bases the assertion upon homology to existing nucleic acids or protein having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion." Utility Examination Guidelines, page 1096), and as applicants argued in their previous responses. Applicants submit that under Fujikawa and the Utility Examination Guidelines, homology of the claimed sequences to one or more proteins that itself has known utility is sufficient to satisfy 35 U.S.C. §101. Applicants have presented data indicating homology between the claimed K+betaM5 sequence and other proteins that have known utility.

In the Final Rejection, the Patent Office attempts to distinguish Fujikawa on its facts, but this argument fails as it does not challenge the salient holding of Fujikawa, namely that "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." Fujikawa at 1565. Applicants have established at least a reasonable correlation. Applicants further note that the Utility Examination Guidelines present Fujikawa in the context of a discussion of utility based on homology, presenting yet another reason why the Patent Office's attempts to distinguish and minimize the holding of Fujikawa fails.

In the first Office Action issued, the Patent Office addressed several asserted utilities and concluded that these utilities were not specific, substantial and/or credible. More particularly, in the first Office Action issued the Patent Office concluded

(a) treatment of a condition is not specific or substantial;

(b) use of the claimed sequences in the production of antibodies is not specific;

(c) use of the claimed sequences to produce a variant nucleotide and polypeptide is not substantial or specific;

(d) use of the claimed sequences to identify ligands of the polypeptide encoded by the claimed polynucleotide is not substantial; and

(e) use of the claimed sequences in a tissue typing protocol is not substantial or specific.

The Patent Office maintained these rejections in the Final Rejection of the claims for the same reasons. Although numerous specific, substantial and credible utilities are presented in the Specification, for brevity and convenience, applicants confine their arguments here to those asserted utilities identified by the Patent Office.

Summarily, applicants are of the position that the Patent Office did not give due consideration to the detailed disclosure of these asserted utilities and to the other utilities recited in the Specification. Applicants respectfully submit that the Patent Office has applied an overly restrictive standard that is inconsistent with the letter and spirit of the statute, that is inconsistent with the applicable case law and that is inconsistent with current Patent Office protocol.

Applicants now address each of the Patent Office's analyses of the asserted utilities in turn.

The Treatment of a Disease Condition with a Ligand of the Claimed Sequences is a Specific, Substantial and Credible Utility

The Patent Office argued in both the first and final Office Actions that applicants' asserted utility of treatment of a condition, such as a potassium ion-channel polypeptide deficiency, using ligands of the claimed sequences is not specific or substantial, and is unsupported. However this argument by the Patent Office ignores the guidance and disclosure provided in the Specification supporting this asserted utility.

Applicants note that on page 48, lines 30-34 of the Specification, it is stated "[b]ased on the expression pattern of this novel sequence, diseases that may be treatable with agonists and/or antagonists for K+betaM5 including, but not limited to, epilepsy, Bartter's syndrome, persistent hyperinsulinemic hypoglycemia of infancy, hyperkalemia and hypokalemia, cystic fibrosis and hypercalciuric nephrolithiasis." Additional disclosure is found on page 49, line 36 to page 50, line 9 of the Specification, which applicants present after discussing the association of the claimed sequences with the NF-kB pathway: "antagonists of K+betaM5 may be useful in the

treatment of inflammatory diseases including rheumatoid arthritis, asthma, multiple sclerosis, osteoarthritis, among others. Thus, agonists of K+betaM5 may enhance an individual's immunity after vaccination. In contrast, antagonists of this K+betaM5 could be useful for treating T-cell mediated autoimmune diseases such as rheumatoid arthritis, multiple sclerosis, psoriasis, among others."

Therefore, the specification discloses conditions in which a condition, such as a condition associated with a deficiency in a polypeptide or polynucleotide of the present invention, might be treated using a modulator produced in accordance with the present invention.

The Patent Office also concluded that the above-recited diseases "surely do not involve perturbations in the K+betaM5 peptide disclosed in the instant Application." Final Rejection, page 5. However, the Patent Office does not supplement this position with any references, making this assertion merely suspicion and unsupported speculation.

The Use of the Claimed Sequences in the Production of Antibodies is Specific, Substantial and Credible

In the Final Rejection, the Patent Office states "the usefulness of antibodies rests on the utility of the protein against which they are made." Final Rejection, page 6. This rejection was presented in the first Office Action and maintained in the Final Rejection.

Applicants respectfully submit that the utility of the K+betaM5 polypeptide itself was established in the Specification, as highlighted in applicants' previous responses and in this brief. In this regard, applicants note that in addition to the homology data described herein above, tissue profiling was performed that localized expression of the claimed polypeptides to testis, spinal cord, lymph node, heart, uterus, and to a lesser extent, in small intestine, stomach, prostate, and kidney (see Figure 8). Expanded expression profiling (see Figure 9) confirmed high expression in testis. Further, RNAi data on protein CG10465, the putative Drosophila ortholog of the claimed human K+betaM5, suggests that in Drosophila this protein regulates the LPS-response pathway (see, e.g., page 49, lines 16-26, of the Specification and Example 6, page 251).

The Patent Office stated "[a]n applicant may therefore patent all antibodies that bind to a particular polypeptide or epitope, provided it itself has a function." Final Rejection, page 6. In view of the characterization of the claimed K+betaM5 sequences, applicants submit that antibodies to K+betaM5 have a wide variety of applications, ranging, for example, from protein purification to therapeutic applications, and including those asserted utilities identified by the Patent Office, all of which are discussed in the Specification. In view of this, applicants submit that the generation and use of antibodies to the claimed sequences is a specific, substantial and credible utility.

The Use of the Claimed Sequences in the Production of Variant K+betaM5 Nucleotides and Polypeptides is Specific, Substantial and Credible

The thrust of the Patent Office's arguments regarding the asserted utility of producing variants of the claimed sequences appears to be the contention that the asserted utility is not present in a mature form that can be used in a "real world" sense. Applicants disagree

Applicants submit that the Patent Office has not properly acknowledged the description of the claimed polypeptides and polynucleotides in the specification. When this knowledge is taken into account, it is clear that the claimed sequences can be employed to make, study and use variants of the claimed polypeptides and polynucleotides. Such variants can be employed in the same roles as the characterized claimed polypeptides and polynucleotides. For instance, a variant prepared in accordance with the present invention might exhibit an enhanced activity that might be desirable in a given application of the sequences of the present invention. Applicants submit that this is a specific, substantial and credible use for the claimed variants.

Apparently, it is the Patent Office's position that since no variant of the claimed polypeptide was actually produced and characterized, the asserted utility of producing and using variants of the claimed sequence is unsupported ("Applicants have not provided any guidance or working examples regarding mutations that have been made to the polynucleotide encoding K+betaM5 and the resultant activity of the channel." Final Rejection, page 7.). Applicants respectfully note that there is no requirement that an applicant provide any working examples.

Thus, applicants submit that a rejection based on the Patent Office's argument that a variant of the claimed polypeptide was not produced and characterized does not support its position that the asserted utility is not specific, substantial and credible.

The specification provides a nucleic acid sequence encoding the claimed K+betaM5 polypeptide, as well as the sequence of the encoded polypeptide. Characterization data is also included. Given this disclosure, one of ordinary skill in the art would readily be able to use the claimed sequences to make variants and fragments useful for the various purposes discussed in the Specification.

As noted herein above, applicants submit that the polypeptides and polynucleotides of the present invention have been described in the specification to a degree that one of ordinary skill in the art would not doubt applicants' characterization of the sequences and applicants asserted utilities. This knowledge of the sequences can be employed to make, study and use variants of the claimed polypeptides and polynucleotides. Indeed guidance is provided in the Specification in preparing such variants (see, e.g., page 78, line 1 through page 92, line 27, including Table 3 presented therein). Such variants can be employed in the same roles as the characterized claimed polypeptides and polynucleotides. For instance, a variant prepared in accordance with the present invention might exhibit an enhanced activity that might be desirable in a given application of the sequences of the present invention.

For at least these reasons, applicants remain of the opinion that the use of the claimed sequences to make and/or identify variants of the claimed sequences is specific, substantial and credible.

Applicants further note that in the Final Rejection, the Patent Office does not appear to address the utility of the claimed variants, focusing instead on an enablement analysis. If the Patent Office is agreeing with applicants that the asserted utility of generating and using the claimed variant sequences is specific, substantial and credible, which appears to be the case, then the rejection of the claims under 35 U.S.C. §101 must be withdrawn.

The Use of the Claimed Sequences to Identify Modulators of a Polypeptide Encoded by the Claimed Polynucleotide is Specific, Substantial and Credible

The Patent Office's argument regarding this recited utility appears to be that it is the Patent Office's contention that the claimed sequence has not been characterized and that binding sites have not been identified. In view of this belief, the Patent Office then concluded that applicants' asserted utility of using the claimed sequences in binding assays in the identification and/or development of K+betaM5 modulators is not substantial. Applicants respectfully disagree.

The sequences of the present invention have various degrees of similarity and identity to several proteins, which have been characterized and have or may have utility with respect to some disease conditions. Accordingly, applicants submit they are not merely investigating the claimed sequences for possible uses, but rather that the claimed sequences have the specific, substantial and credible uses set forth above, including in the identification and development of K+betaM5 modulators.

Applicants again submit that a list of diseases and conditions that may be treatable with a modulator of the claimed sequence is disclosed in the Specification. In this regard applicants note that the Specification discloses situations (e.g., disease conditions) in which it may be desirable that the activity of the claimed sequence is up-regulated and other situations in which it may be desirable that the activity is down-regulated. Modulators can be identified that exhibit either of these properties, or an entirely different property. Applicants note that, although screening assays can be performed with a modulator of any sequence, such assays will not identify modulators of the claimed K+betaM5 sequence.

Guidance is provided in the Specification for the preparation of formulations comprising such a modulator that could be employed in the treatment of a disease in addition to a discussion of dosing procedures. Applicants further note that the Specification provides guidance on how one of ordinary skill in the art could run assays for ligand binding, for example in the section of the Specification beginning on page 210, line 21 entitled "Binding Activity." In this section applicants provide direction on how to set up and perform various ligand binding assays

designed to identify modulators of K+betaM5 activity. In view of this disclosure, applicants submit that the asserted utility is specific.

This is also a substantial utility. According to the Utility Guidelines, an assay method for identifying compounds that themselves have a substantial utility defines a "real world" context of use. Utility Guidelines, page 6. Under this test, compounds identified by the claimed method meet the substantial utility test because they are useful for treating specific disorders, such as epilepsy, Bartter's syndrome, persistent hyperinsulinemic hypoglycemia of infancy, hyperkalemia and hypokalemia, cystic fibrosis and hypercalciuric nephrolithiasis.

Summarily, applicants submit the Specification provides a function for the claimed sequences, which is supported by the homology and RNAi data presented therein. Applicants are of the position that this data, as well as the other disclosure presented in the Specification, supports applicants' characterization of the claimed sequences. When coupled with the specific disclosure regarding binding assays and methods of identifying modulators presented in the Specification, applicants submit that this cumulative description supports applicants' contention that the asserted utility is specific, substantial and credible.

The Use of the Claimed Sequences in Tissue Typing is Specific, Substantial and Credible

In the Final Rejection, the Patent Office states the asserted utility of employing the claimed sequences in tissue typing "is not substantial because one skilled in the art would not readily use the nucleotide sequences for tissue-typing in a real world sense as the protein is not specific to one tissue and is not associated with any disease or disorder." Final Rejection, page 8. Consequently, it is the Patent Office's position that the asserted utility of tissue typing is not specific or substantial. Applicants disagree and submit that by providing the claimed sequences and the characterization of the claimed sequences, one of ordinary skill in the art would be able to employ the sequences in a tissue typing protocol.

Applicants submit that tissue typing is a "real world" context of use and is supported by the Specification. First, applicants note that data provided in the specification indicates the claimed polypeptide is expressed significantly in spinal cord, lymph node, heart, uterus, and, to a

lesser extent, in small intestine, stomach, prostate, and kidney (see Figures 8 and 9). Applicants submit that even if the claimed sequence is expressed in more than one tissue, this does not invalidate the asserted utility. Applicants submit that at a minimum, one of ordinary skill in the art could use the claimed sequences in typing the tissues in which K+betaM5 is expressed, and applicants have provided this information in the Specification.

The Patent Office also argues "the supposed association with the NF-kB pathway is not substantial, even if confirmed, because the pathway is a general one upon which many transduction pathways converge." Final Rejection, page 8. Applicants respectfully submit that it is not relevant that the NF-kB pathway is general; applicants submit they have associated the claimed sequences with this pathway, which is known to be associated with a range of disorders, including immune disorders. Applicants recite several immune system conditions, for example, rheumatoid arthritis, asthma, multiple sclerosis, osteoarthritis, in which the claimed polypeptide might be implicated. Applicants submit this represents yet another specific, substantial and credible utility.

Even assuming, *arguendo*, that the Patent Office's characterization of the claimed sequences and the homologous proteins is accurate, it is not the law that sequences showing homology to the claimed sequences cannot be classified in a family in which the members may have divergent functions, which also appears to be the Patent Office's position. Applicants' burden is simply to show that the claimed sequences either have demonstrated utility or can be shown to have homology to sequences having demonstrated utility, as in the present case. Applicants have clearly met their burden in this regard.

Further, it is well established that nucleic acids and proteins encoded thereby, such as K+betaM5, which are shown to be expressed in various tissues, may be biological targets for the treatment of disease states associated with such tissues. Indeed, the patent literature is replete with such examples. Accordingly, applicants submit that the present invention clearly has specific and substantial utility. The use of the claimed molecules as biological targets alone satisfies this requirement.

Lastly, applicants submit that applicants need only demonstrate a single use for the claimed sequences. Applicants have done this. For example, specific, substantial and credible utility is established at the very least by the use of the claimed compounds as molecular weight markers ("In the very least, the polynucleotides of the present invention can be used as molecular weight markers on Southern gels " Specification, page 175, lines 21-22). Applicants also note the range of additional utilities provided in the Specification that the Patent Office did not consider, for example the use of the claimed sequences in as diagnostic probes for the presence of a specific mRNA in a particular cell type, as a probe to 'subtract-out' known sequences in the process of discovering novel polynucleotides, for selecting and making oligomers for attachment to a "gene chip" or other support, to raise anti-DNA antibodies using DNA immunization techniques, and as an antigen to elicit an immune response.

Simply put, applicants need to assert only a single specific, substantial and credible utility. They have done so and the rejection of the claims under 35 U.S.C. §101 should be reconsidered and withdrawn.

B. THE SPECIFICATION ENABLES CLAIMS 21-32 AND 34-40 AND MEETS THE REQUIREMENTS OF 35 U.S.C. §112, FIRST PARARGRAPH.

In the Final Rejection, the Patent Office maintained its rejection of Claims 21-32 and 34-40 under 35 U.S.C. §112, first paragraph, as not being enabled. The Patent Office contends that the claimed sequences have not been adequately characterized and lack utility; therefore, the Patent Office argues, one skilled in the art would not know how to make and use the claimed invention. Applicants respectfully disagree.

For the reasons presented herein above, applicants submit that the claimed K+betaM5 sequences are characterized to a degree that one of ordinary skill in the art would not doubt applicants' statements regarding the sequences identity and function. Applicants point to the homology data and RNAi in support of their position.

In view of the characterization of K+betaM5, applicants restate the above arguments that the claimed invention is indeed supported by specific, substantial and credible utility. Examples

of such utilities include those identified by the Patent Office, namely (a) to produce molecules useful for the treatment of a condition, of which the specification identifies several, (b) for the production of antibodies, (c) to produce variant nucleotides and polypeptides, (d) to identify ligands of the polypeptide encoded by the claimed sequences and (e) in tissue typing, among other uses. As argued above, Applicants submit that these and other utilities are supported by the Specification as filed.

In view of applicants' characterization of the claimed K+betaM5 sequences, applicants submit the Patent Office's rejection of the claims under 35 U.S.C. §112, first paragraph, enablement, cannot stand. Accordingly, applicants respectfully request that the rejection of the claims under 35 U.S.C. §112, first paragraph, enablement, be reconsidered and withdrawn.

C. CLAIM 21 IS DEFINITE AND MEETS THE REQUIREMENTS OF 35 U.S.C. §112, SECOND PARAGRAPH

The Patent Office rejected claim 21 as indefinite. The Patent Office asserted that the term "stringent" is not defined in the claim. The Patent Office also contends the claim itself must define the use of the word. Applicants respectfully disagree with the Patent Office's position.

Applicants note the discussion beginning on page 18, line 33 and ending on page 19, line 5 of the Specification, wherein applicants explicitly define "stringent hybridization conditions." Further discussion and definition of "stringent conditions" is provided in the Specification in the section beginning on page 74, line 8 and continuing through page 77, line 12, including Table 2 presented therein.

The Court of Appeals for the Federal Circuit stated "the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement [is] as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2." Exxon Research and Engineering Co. v. U.S., 265 F.3d 1371, 1375 (Fed. Cir. 2001) citing Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993). In the present case, the term "stringent" is defined in the

Specification. Applicants submit there is no legal requirement that this definition appear in the claims when it is presented explicitly in the Specification in such a way that those of ordinary skill in the art would be apprised of the metes and bounds of claim 21 upon consideration of the Specification.

CONCLUSION

For the reasons set forth above, Applicants respectfully submit that the present specification satisfies the utility requirement of 35 U.S.C. §101, the definiteness requirement of 35 U.S.C. §112, second paragraph, and the requirements of 35 U.S.C. §112, first paragraph. Accordingly, the Board is respectfully requested to reverse the appealed decisions of the Examiner.

Respectfully submitted,

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(9) APPENDIX

Claims Involved in the Appeal

21. An isolated nucleic acid molecule comprising a polynucleotide sequence selected from the group consisting of:

(a) an isolated polynucleotide encoding a polypeptide comprising amino acids 1 to 343 of SEQ ID NO:24 including the start codon;

(b) an isolated polynucleotide encoding a polypeptide comprising amino acids 2 to 343 of SEQ ID NO:24 minus the start codon;

(c) an isolated polynucleotide encoding a polypeptide comprising amino acids 146 to 241 of SEQ ID NO:24;

(d) an isolated polynucleotide which represents the complimentary sequence of (a), (b), (c), or fragment thereof; and

(e) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(d), wherein said polynucleotide does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues.

22. The isolated nucleic acid molecule of claim 21, wherein said polynucleotide is (a).

23. The isolated nucleic acid molecule of claim 22, wherein said polynucleotide comprises nucleotides 23 to 2154 of SEQ ID NO:23.

24. The isolated nucleic acid molecule of claim 21, wherein said polynucleotide is (b).

25. The isolated nucleic acid molecule of claim 24, wherein said polynucleotide comprises nucleotides 26 to 2154 of SEQ ID NO:23.

26. The isolated nucleic acid molecule of claim 21, wherein said polynucleotide is (c).

27. The isolated nucleic acid molecule of claim 26, wherein said polynucleotide comprises nucleotides 436 to 723 of SEQ ID NO:23.

28. The isolated nucleic acid molecule of claim 21, wherein said polynucleotide is (d).

29. The isolated nucleic acid molecule of claim 21, wherein said polynucleotide is (e).

30. A recombinant vector comprising the isolated nucleic acid molecule of claim 21.

31. A recombinant host cell comprising the vector sequences of claim 30.

32. A method of making an isolated polypeptide comprising:

(a) culturing the recombinant host cell of claim 31 under conditions such that said polypeptide is expressed; and

(b) recovering said polypeptide.

34. The isolated polynucleotide of claim 21 wherein said nucleic acid sequence further comprises a heterologous nucleic acid sequence.

35. The isolated polynucleotide of claim 34 wherein said heterologous nucleic acid sequence encodes a heterologous polypeptide.

36. The isolated polynucleotide of claim 35 wherein said heterologous polypeptide is the Fc domain of immunoglobulin.

37. An isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 60.0% identical to a sequence provided in claim 21, wherein percent identity is calculated using a CLUSTALW global sequence alignment.

38. The isolated polynucleotide of claim 37 wherein said nucleic acid sequence further comprises a heterologous nucleic acid sequence.

39. The isolated polynucleotide of claim 38 wherein said heterologous nucleic acid sequence encodes a heterologous polypeptide.

40. The isolated polynucleotide of claim 39 wherein said heterologous polypeptide is the Fc domain of immunoglobulin.